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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,119	03/11/2004	Yih-Lin Chung	13206-004002 / 0668-A2034	8809
26161 7590 12/19/2006 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER HUGHES, ALICIA R	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		12/19/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/798,119	Applicant(s) PAMUKUE ET AL	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specie Election

This application contains claims directed to the following patentably distinct species, and a choice of one from each of the following four species is required to be elected for examination:

- 1) Chemotherapy and radiotherapy (See sub-specie election requirement, *infra*).
- 2) Proliferating malignant disease and nonmalignant disease (See sub-specie election requirement, *infra*).
- 3) Histone hyperacetylating agent that is trichostatin A, trichostatin C, oxamflatin, trapoxin A, FR901228, apicidin, HC-Toxin, WF27082, chlamydocin, salicylihydroxamic acid, suberoylanilide hydroxamic acid, azelaic bishydroxamic acid, azelaic-1-hydroxamate-9-an-ilide, M-carboxycinnamic acid, bishydroxamide, 6-(3-chlorophenylureido)carp-oic hydroxamic acid, MW2796, MW2996, sodium butyrate, isovalerate, valerate, 4-phenylbutyrate, sodium phenylbutyrate, propionate, butrymide, isobutyramide, phenylacetate, 3-bromopropionate, valproic acid, tributyrin, MS-27-275 or the 3'-amino derivatives thereof, depudecin, and scriptaid (See sub-specie election requirement, *infra*).
- 4) Pharmaceutical carriers, that are cream, ointment, gel, paste, powder, lotion, patch, suppository, liposome formation, a suspension, mouth wash, an enema, an injection solution, and a drip infusion (See sub-specie election requirement, *infra*).

The species are independent or distinct because, in the case of chemotherapy, chemical agents or drugs that are selectively toxic to the causative agent are used for the treatment of disease while with the case of radiotherapy, radiation particularly selective irradiation with x-rays or other ionizing radiation or by ingestion of radioisotopes, is used for the treatment of

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disease. As a result of the variation, both radiotherapy and chemotherapy require different fields of search and yield different results. In the case of proliferating malignant and non-malignant diseases, a search for one would not necessarily yield results for another, because proliferating malignant diseases are cancerous whereas non-malignant diseases are not. In the case of the hyperacetylating agents because they have variable functions and means of working, for example trichostatin A is an antifungal antibiotic with cytostatic and differentiating properties known as a potent and specific inhibitor of histone deacetylase (HDAC) activity while FR901228 is a depsipeptide known to show antiproliferative and apoptotic effects in various malignancies including small cell lung cancer by inducing caspase-dependent apoptosis via the mitochondrial pathway rather than the death receptor pathway, a search of one would not necessarily yield results for another.

In the case of the pharmaceutical carriers, a search for one will not necessarily yield results for the other, because the carriers are known for their multi-functionality, for example the patch being utilized as a form of birth control in addition to being utilized as a deterrent against smoking and an ointment being utilized to treat infections while suppositories may be utilized to treat conditions such as constipation and diarrhea.

The applicant is required under 35 U.S.C. 121 to elect a single disclosed species within each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In addition to the above election requirement under 35 U.S.C. 121, if Applicant elects radiotherapy, Applicant must elect a subspecies that is either teletherapy, brachytherapy, or ionizing radiation. If Applicant elects proliferating malignant disease, Applicant must elect one subspecies that is listed in claim 5. If Applicant elects

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nonmalignant disease, Applicant must elect one subspecies that is listed in claim 6. If Applicant elects a conjugated antibody, Applicant must elect one subspecies that is either Trastuzumab, c225, Rituximab, or Cetuximab. If Applicant elects a chemotherapeutic agent, Applicant must elect a subspecies that is listed in claim 19. If Applicant elects an angiogenesis agent, Applicant must elect a subspecies that is either thalidomide, SU5416, SU6668, Thrombospondin-1, endostatin or angiostatin. If Applicant elects an antibiotic, Applicant must elect one subspecies that is either Ganciclovir, Acyclovir, or Famciclovir. As noted with the species above, so too, a search for one subspecies will not necessarily yield results for another. Currently, claim 1 is generic. In considering the invention, the Examiner is unclear, based on reading generic claim 1, on whether Applicant intends the composition therein to contain a second agent. In addition to the above election requirement under 35 U.S.C. 121, if Applicant intends the composition associated with the method in claim 1 to contain a second agent, Applicant must elect a subspecies that is either: a cytokine, interleukin, anti-cancer agent, anti-neoplastic agent, an anti-angiogenesis agent, chemotherapeutic agent, antibody, conjugated antibody, immune stimulant, antibiotic, retinoic agent, a tyrosine kinase inhibitor, hormone antagonist, or growth stimulant.

Currently, claims 1-21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected in each group consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Applicant is advised that in order for the reply to this requirement to be complete, it must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the

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application. Any amendment of the inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

27 November 2006

ARH

 12/11/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER